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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
YOUNG, MICAH PAUL	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,054	SPEITLING, ANDREAS WERNER	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,9,11-13,17-19,22,23,25-27 and 29-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9,11-13,17-19,22,23,25-27 and 29-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Remarks dated 1/26/05

Claim Objections

1. Claim 29 is objected to because of the following informalities: The claim is dependent from claim 28, which is canceled. Appropriate correction is required.

2. Claim 32 is objected to because of the following informalities: In line 3, layer is misspelled "payer". Appropriate correction is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 25, 26, and 29-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Pratt et al (USPN 4,849,223 hereafter '223). The claims are drawn to a device comprising a body with a sterile surface that is coated with a layer of antibiotic silver ions.

3. The '223 discloses various medical device and implant materials consisting of metallic silver combined with titanium oxide or tantalum oxide (abstract). The antimicrobial coating material comprises silver ions (col. 3, lin. 5- 20, lin. 50 –56; col. 4, lin. 33 – 40; examples). The device also comprises various oxides including tantalum oxide in the coating, as well as hydroxyapatite (col. 3, lin. 1-5). The coating comprises silver ions mixed with tantalum oxide (col. 2, lin. 51 – col. 4, lin., 33). The surface of the device can be smooth dependent upon the

intended use of the device (col. 4, lin. 8 – 13). The coating material can also be incorporated into bone cements so that the cement would produce an antimicrobial effect once in the body (*Id.*). The reference also teaches that the silver ions can be in admixture with hydrated oxides such as magnesium (col. 2, lin. 60-65, col. 4, lin. 13-30). The surfaces of the devices are chlorinated which sterilizes the surface before application of the coating (col. 4, lin 1-5). The reference also discloses a method for making the device where oxides are incorporated into the coating. These disclosures render the claimed anticipated.

4. Claims 25-27, are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobson et al (USPN 5,180,585 hereafter '585).

5. '585 teaches an antimicrobial coating composition. The composition can comprise silver ions, while the substrate can comprise polyetherether ketone (PEEK) and polylactic acid. The antimicrobial composition can be incorporated or coated onto medical devices for implantation such as sutures, or for dental purposes (col. 4, lin. 18 – 30; col. 5, lin. 33 – 40; col. 9, lin. 12-15; col. 11, lin. 36 – 60). The coating composition comprises hydrous oxide, which aid in the release of the antimicrobial agents. The tertiary coatings are resorbable and release the antibacterial agents. These oxides include aluminum, magnesium and zirconium (col. 5, lin. 5-15). The examples teach processes making of the coating comprising coating the antimicrobial ions with layers of hydrous oxides depending on the application (Examples). These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 9, 11-13, 17-19, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Davidson (USPN 5,685,306 hereafter '306), Pratt et al (USPN 4,849,223 hereafter '223) and Jacobson et al (USPN 5,180,585 hereafter '585). The claims are drawn to a medical device comprising a metallic surface and an antimicrobial coating. The coating releases silver ions and can comprise various plastics and ceramics.

2. '306 discloses medical implants comprising metal and a coating where antimicrobial agents can be applied. The coating comprises ceramic like coatings such as titanium zirconium oxides, and diamond-like carbon (col. 6, lin. 37 – 53; col. 7, lin. 55 – 60). One of the embodiments of the invention of the reference is that of a pacemaker lead, electrical signal transmitter, or a defibrillator. An external source would apply the electrical voltage in the defibrillator and signal transmitter embodiments. In this embodiment electrical voltages would

be applied to the surfaces of the device, electrostatically charging the surface of the devices (col. 12, lin. 1 – col. 13, lin. 63). The reference however lacks disclosure of silver zeolites.

3. '223 teaches an antimicrobial coating material for medical devices. The medical devices can have rubber or latex substrates. The antimicrobial coating material comprises silver ions (col. 3, lin. 5- 20, lin. 50 –56; col. 4, lin. 33 – 40; examples). The device also comprises various oxides including tantalum oxide in the coating. The coating comprises silver ions mixed with tantalum oxide (col. 2, lin. 51 – col. 4, lin., 33). The surface of the device can be smooth dependent upon the intended use of the device (col. 4, lin. 8 – 13). The coating material can also be incorporated into bone cements so that the cement would produce an antimicrobial effect once in the body (*Id.*). The reference also discloses a method for making the device where oxides are incorporated into the coating. The reference also discloses polyvinyl chloride as a possible polymer, to be incorporated into a coating layer, but does not disclose the specific plastics of applicant.

4. '585 teaches an antimicrobial coating composition. The composition can comprise silver ions, while the substrate can comprise polyetherether ketone (PEEK) and polylactides. The antimicrobial composition can be incorporated or coated onto medical devices for implantation such as sutures, or for dental purposes (col. 4, lin. 18 – 30; col. 5, lin. 33 – 40; col. 9, lin. 12-15; col. 11, lin. 36 – 60). The coating composition comprises hydrous oxide, which aid in the release of the antimicrobial agents. The tertiary coatings are resorbable and release the antibacterial agents. These oxides include aluminum, magnesium and zirconium (col. 5, lin. 5-15). The examples teach processes making of the coating comprising coating the antimicrobial ions with layers of hydrous oxides depending on the application (Examples).

5. Regarding the polish of the metal surface, it is the position of the examiner that such a limitations does not impart patentability on the instant claims. The claims are drawn to a final product comprising a coating and metallic ions. Applicant has yet to provide a patentable distinction between an unpolished or polished surface. The devices of the prior art have substrates with coatings comprising resorbable components and antimicrobial metallic ions, identical to that of the instant claims. Applicant is invited to provide evidence of criticality to the polishing steps, since the surfaces are coated with polymers, and metallic ions. Until such criticality is established, the claims will remain obviated by the prior art.

6. A skilled artisan would have been motivated to combine the suggestions of the prior art. A skilled artisan would have been motivated to coat the stent of '306 with either the coating compositions of '223 or '585 in order to ward off possible infection during and after implantation. Since a ceramic coating is suggested by '306, '223 would be an obvious choice since hydroxyapatite is disclosed as a possible substrate. Also equally useful as coating substrates are plastics such as polyvinyl chloride, which are useful along with the PEEK of '585. The silver zeolites would have provided improved antimicrobial qualities to the polished metal alloy surface of '306 as well. It would have been obvious to a skilled artisan to coat the device of '306 with either of the coatings taught by '223 or '585, at the time of the invention, with an expected result of a medical device capable of fighting off infection upon implantation or medical use.

Response to Arguments

8. Applicant's arguments filed 1/26/05 have been fully considered but they are not persuasive. Applicant argues that:

a. The art does not teach a coating mixture where antimicrobial agents are mixed with magnesium

b. There is no motivation to combine '306, '223 and '585.

Regarding argument a., the Examiner drawn applicant's attention to the amended claims, which do not in fact recite a coating composition, requires magnesium and silver or copper ions. The claims have been amended adding magnesium to the large Markush group of possible coating substrates, and removes magnesium from the group of possible additives. This amendment does not require magnesium any more than any other member of the coating Markush group, and does not overcome the rejections of record. Pratt teaches a medical device coated with an admixture of silver ions and hydrated oxides including magnesium (col. 2, lin. 55-col. 4, lin. 33). It is the position of the Examiner that these disclosures anticipate the instant claims.

Regarding argument b., it is the position of the Examiner there exists motivation to combine the references. The '306 patent provides a metallic wire coated with a polymeric or ceramic insulating layer such as titanium zirconium carbide or nitrate (col. 12, lin. 4-29). These wires carry electronic current and surface charges since they operate as lead wires for pacemakers and other electronic equipment. The reference is silent to antibacterial silver zeolites, however '223 and '585 teach antibacterial silver zeolites coated devices. It would be well within the level of skill in the art to substitute either of the coatings for the ceramic coating

of '306 in order to fight possible infections after implantation of the pacemaker leads. For these reasons the claims remain obviated and anticipated by the art.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1618

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